Vaccine Transport SOP

Purpose: To ensure the vaccine cold chain during vaccine transport is maintained for optimum potency.

- Review and update document annually, when vaccine management policies change, and when staff with designated vaccine management responsibilities change.
- Post on/near vaccine storage unit(s) and where vaccines are packaged for transport.
- **All staff transporting vaccines including "only in emergency settings" must read, sign, and adhere to the protocols described in this document.**

TRANSPORT SITUATIONS & PACKING METHODS

Transport packing methods differ between 1) Emergency transport and 2) Planned transport such as for off-site clinics, satellite facilities, or re-location of stock. In either case, a portable refrigerator/freezer is always the preferred method.

Emergency transport requires either portable vaccine storage units (portable vaccine refrigerator/freezer), qualified containers and pack-outs, or the conditioned water bottle transport system.

- For step-by-step guidance on packing a cooler for emergencies using the conditioned water bottle method, see CDC's Packing for Emergency Transport.

Planned transport requires either portable refrigerators/freezers or qualified containers and pack-outs (e.g., Cool Cubes, TempArmour, etc.). The conditioned water bottle method should not be used for planned transport.

- Follow instructions specific to the portable refrigerator/freezer or qualified container/pack-out used.

Anytime your practice is moving vaccines off-site, regardless the transport method unit you are using, the **vaccines must be monitored by an external digital data logger device**. Do not add vaccines until the external data logger device is reading in-range temperatures and **never** transport refrigerated vaccines on **frozen ice packs**.

Transport Method	Emergency Transport	Planned Transport (Off-site Clinic, Satellite Facility, or Relocation of Stock)
Portable Vaccine Storage Unit (preferred)[1]	Yes	Yes
Qualified Container and Pack-out[2]	Yes	Yes
Conditioned Water Bottle Transport System[3]	Yes	No* (see one exception below)

1. **Portable Vaccine Storage Unit:** A type of powered refrigerator, freezer or Ultra-Cold (UTC) freezer unit specifically designed and purpose built for use during vaccine transport. These units should include an internal fan, sturdy handles, lockable latch, and a programmable digital thermostat. Despite having a programmable digital thermostat, an external digital data logger is still required for vaccine transport. These active units are "qualified" to maintain desired temperatures for **4-5 days** in the event of a power loss. For proper use, follow directions stated in manufacturer instructions. While the MDPH Immunization Division **does not recommend or endorse** a specific portable vaccine storage, here are a few brands that meet MDPH qualifications: 100-Liter or 35-Liter Portable Medical FridgeFreeze; BioFridge; AccuCold

2. **Qualified Container and Pack-out:** A type of container and supplies specifically designed and purpose built for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time (traditionally **3-5 days**) without the use of electricity, ice or buffering materials. For proper use, follow directions stated in manufacturer instructions. While the MDPH Immunization

Division **does not recommend or endorse** a specific qualified container or pack-out, here are a few brands that meet MDPH qualifications: The TempArmour™ Vaccine Carrier; Vericor Cool Cube™ 96 at Refrigerated Temps

3. ***Conditioned Water Bottle Transport Method:** Method outlined according to CDC's Packing for Emergency Transport. This is for **emergency transport only**; the only time that this method should be used for planned transport (i.e., off-site clinics, transport to a satellite facility, or relocation of stock) is if there is a designated pharmaceutical grade units located on site of vaccination where the vaccines can be stored during the clinic. Traditional hard sided coolers are not meant to be opened and closed frequently therefore increasing the likelihood of non-viable vaccines if this method is treated the same as a qualified container and pack out or a portable fridge. This method can maintain appropriate temperatures for up to **8 hours** if the cooler is not repeatably opened and is packed correctly.
    - To pack the **refrigerated** vaccines for transport, place 16.9-ounce **conditioned** frozen water bottles across the bottom of the cooler. These water bottles will be kept frozen and then, prior to transport, they will be conditioned (as per CDC vaccine transport guidelines) in a sink with lukewarm water until they thaw to the point that the ice in each water bottle can spin freely in the bottle. Pack enough water bottles to fit snugly across the bottom of the cooler. Place a piece of corrugated cardboard on top of the water bottles, followed by a piece of thick bubble wrap. The vaccines and the buffered probe of the transport data-logger (which should be kept in the fridge) should then be placed on top of the bubble wrap followed by another identical piece of bubble wrap, another piece of cardboard and then more 16.9 oz conditioned frozen water bottles. The data logger should be kept outside the cooler and attached to the top of the cooler for easy viewing. CAUTION: DO NOT ADD VACCINES INTO THE TRANSPORT COOLER UNTIL THE DDL IS READING IN-RANGE TEMPERATURES (+2.0° C to +8.0° C) AND NEVER TRANSPORT VACCINES ON FROZEN ICE PACKS.

GUIDANCE SPECIFIC TO FROZEN VACCINE (EXCLUDING ULTRA-COLD FROZEN VACCINE)

CDC recommends transport of vaccine at refrigerator temperatures whenever possible. If vaccine is transported frozen:

- A portable freezer is BEST practice. All other options increase the likelihood of a vaccine excursion.
- Use a portable vaccine freezer or qualified container and pack-out that maintains temperatures between-50.0° C to -15.0° C (-58.0° F to +5.0° F).
- Do NOT use dry ice, even for temporary storage or emergency transport.

UPON ARRIVAL AT CLINIC OR BACKUP LOCATION

1. All state-supplied vaccines must have an approved digital data logger (DDL) attached to the vaccine transport cooler at all times during transport. **NEVER MOVE VACCINES WITHOUT THE USE OF A DIGITAL DATA LOGGER TO MONITOR INTERNAL TEMPERATURES OF THE TRANSPORT COOLER.**
2. Vaccines transported using conditioned water bottles in a cooler should only be transported to one location and immediately move vaccines into pharma grade fridge at the final destination.
3. Any vaccines that need to be reconstituted should be reconstituted after arrival at the final location and just prior to being administered.
4. Transport single dose vaccine vials whenever possible. If a vaccine is only available in multi-dose vials, draw up that dose of the vaccine last, administer it and immediately return to the fridge/freezer to put the rest of the multi-dose vial back in the unit. Additionally, the multi-dose vial should be unpunctured at the time of transfer to the Mobile Clinic. **Do not transfer open multi-dose vials at any time**.
5. Document the date, time, and temperature on the refrigerator/freezer data-logger on the CDC vaccine transport log when the vaccines are removed from the fridge or freezer and placed in the cooler(s).
6. On arrival to the vaccination location, before opening the cooler or coolers (if both refrigerated and frozen vaccines are being transported), record the date, time, temperature, and initials on the CDC vaccine transport log that should always accompany you for any vaccine transports. **If there is a temperature out of range, immediately stop administering the vaccines and label the storage unit 'DO NOT USE' and contact the Vaccine Unit.**

7. Document the exact time and temperature when vaccines were administered so that, in the event that there is a temperature excursion in the cooler after the vaccines have been given and there are no vaccines left in the cooler, this will be noted in the temperature reporting log. In cases where there are other staff on site helping with vaccination, it must be noted that the person moving the vaccines is ultimately responsible for the vaccines, recording temperatures, times and wastage.
8. Temperature data from cooler transport data loggers must be uploaded to the MIIS (under Transport/Temporary Storage) after each transport. Write the time the vaccines were placed in the cooler and left the cooler in the "notes section" and if there is an excursion also upload the DDL "txt file" to the MIIS for additional context of the excursion.
9. All patients should be contacted on the day of the visit to confirm that they will be getting vaccines before the vaccines are packed in the cooler, in order to minimize any wasted vaccines.

Portable Vaccine Storage Unit (preferred)

Qualified Container and Pack-out

Conditioned Water Bottle Transport System

Vaccine Transport Method and other Transport Supplies				
	Cooler (example)	**Cooler 1**	**Cooler 2**	**Cooler 3**
Transport Method	Conditioned water bottle transport			
Cooler Name	Igloo Hard sided cooler			
Cooler Storage Location	In the closet next to the vaccine storage units			
Fridge or Frozen Vaccines?	Fridge Vaccines			
Other packing materials if needed	8 frozen water bottles in freezer to be conditioned, cardboard and bubble wrap stored inside igloo cooler			
DDL Glycol Bottle Storage Location	Stored in Main Fridge			
DDL Monitor Storage Location	Velcroed to the top of the Main Fridge Cooler			
What type of DDL?	State Issued FridgeTag2L			
Digital Data Logger ID	123456789			

Overall Plan for Mobile Clinics

1. Who (People moving and administering vaccine),
2. What (Which fridge and/or Frozen Vaccines)
3. Where (Different locations)
4. When (The frequency at which you will move vaccines)
5. Why (Purpose of Mobile Clinics or Vaccine Transfer)
6. How (How will you assure all vaccine moved is used and if not used what is the step-by-step plan to prevent vaccine wastage?)

Plan for Vaccines Once at Mobile Clinic

1. Who is responsible for administering the vaccines?
2. What protocols are in place to prevent wastage during the clinic?
3. Where will the vaccines be stored at the Mobile Clinic?

This plan will be reviewed in accordance with the MDPH Vaccine Program regulations and recommendations at least once every year.

This Transport Plan was created and completed by:
Name:
Title:
Date of Completion:
Signature:

Please Note: All staff that are involved in the vaccine transport process at your site should review and sign this SOP.

Date	Employee Name	Employee Signature